IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

CYBERGENETICS CORP.,	)	CASE NO. 5:19-CV-1197
	)	
Plaintiff,	)	
	)	JUDGE SARA LIOI
vs.	)	
	)	
INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH, et al.,	)	MAGISTRATE JUDGE KATHLEEN B. BURKE
	)	
Defendants.	)	
	)	

DEFENDANTS' MOTION TO DISMISS

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STATEMENT OF ISSUES

1) Are patent claims directed to abstract ideas if their focus is on collecting DNA data, analyzing it with a mathematical algorithm, and generating more data?
2) Do patent claims fail to recite an inventive concept if, other than an algorithm, they merely recite generic computer components and routine and conventional preliminary data-gathering steps?
3) Are patent claims that merely recite abstract ideas, generic computer components, and routine and conventional pre- and post-solution steps patent-ineligible under 35 U.S.C. § 101?

SUMMARY OF ARGUMENT

Plaintiff Cybergenetics Corp. sued defendants Institute of Environmental Science and Research Limited and NicheVision Inc. for infringing U.S. Patent Nos. 8,898,021 and 9,708,642. The Complaint alleges infringement of independent claim 1 of each patent, but does not specifically identify infringement of any other claims. The independent claims are representative of all the claims because all are substantially similar and linked to the same concept, with the dependent claims only adding minor limitations.

Defendants move for dismissal under Fed. R. Civ. P. 12(b)(6) on the ground that the claims are ineligible for patent protection under 35 U.S.C. § 101. Patent eligibility under § 101 is a legal determination upon which a district court may rule on a Rule 12(b)(6) motion. Patent eligibility is determined by considering: (1) whether the claims are directed to an abstract idea, and (2) whether the claims contain an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible concept. The use of wholly generic computer implementation cannot transform a patent-ineligible abstract idea into a patent-eligible invention.

The claims here can be distilled to: collecting DNA sample data, guessing possible contributing genotypes, and analyzing the accuracy of the guess. The claims are invalid under 35 U.S.C. § 101 because they are directed to patent-ineligible subject matter and do not recite any "inventive concept" that ensures that the claims amount to significantly more than patents on the ineligible subject-matter itself. The patents' specification makes clear that the claimed invention is directed to mathematical algorithms for analyzing DNA mixture data. Collecting data, analyzing and manipulating it with mathematical algorithms, and displaying results is directed to an abstract idea, which is patent-ineligible. Limiting the algorithm to a particular field of use or technological environment does not make it less abstract. The specification also discloses a mathematical

formula that expresses (in equation form) the relationship of DNA from multiple contributors combined in a mixture, which is a natural law that is also patent-ineligible.

Other than the patent-ineligible concepts, the claims recite generic computer components and well-understood, routine, and conventional pre- and post-solution steps that fail to provide an inventive concept. Such conventional steps include preliminary DNA processing that was routinely performed by forensic laboratories and showing analysis results visually and in a report. Because all claims of the asserted patents fail § 101, Plaintiff's Complaint should be dismissed as a matter of law.

I. INTRODUCTION

Plaintiff Cybergenetics Corp. filed this suit against defendants Institute of Environmental Science and Research Limited ("ESR," a Crown Research Institute owned by the New Zealand Government and thus an instrumentality of a foreign state) and NicheVision Inc. ("NicheVision") (collectively, "Defendants"). (*See* Compl., Doc. No. 1 at 1-2.) ESR has created STRmix, a forensic software program that analyzes, interprets, and resolves DNA mixtures. (*See id.* at ¶11.) Plaintiff's suit alleges that NicheVision distributes STRmix in the United States. (*Id.* at ¶¶ 7, 11.) The suit alleges that Defendants infringe U.S. Patent Nos. 8,898,021 (the "'021 Patent," Compl. Ex. A, Doc. No. 1-1) and 9,708,642 (the "'642 Patent," Compl. Ex. B, Doc. No. 1-2) (collectively, the "Patents-in-Suit"). (Compl., Doc. No. 1 at ¶2.) However, because the Patents-in-Suit attempt to claim abstract ideas that are ineligible for patent protection under 35 U.S.C. § 101, Defendants respectfully move for dismissal of this suit under Fed. R. Civ. P. 12(b)(6).

II. PATENTS-IN-SUIT

A. Prosecution History

The Patent-in-Suit family has a long and eventful history before the U.S. Patent and Trademark Office ("USPTO"). The '021 Patent was first applied for in February 2001 (as application no. 09/776,096). (Doc. No. 1-1 at 19.) After that application was rejected by the USPTO Examiner, the applicant, Mark Perlin, responded arguing against the Examiner's rejections and amending the claims. (*See* '021 Patent Transaction History,[1] attached herein as

[1] In ruling on a Rule 12(b)(6) motion, a court may consider matters of public record and materials subject to judicial notice. *Taylor v. KeyCorp*, 678 F. Supp. 2d 633, 638 (N.D. Ohio 2009). The patent prosecution history before the USPTO is such material. *See Hoganas AB v. Dresser Indus.*, 9 F.3d 948, 954 n. 27 (Fed. Cir. 1993). Furthermore, the Patents-in-Suit are central to Plaintiff's claims, and the Complaint refers to their prosecution (*see* Compl., Doc. No. 1 at 3-4 (¶¶ 12-13)). *See Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008).

Exhibit 1, at p. 4.) The Examiner again rejected the application, and the applicant again responded with arguments and further claim amendments. (*See id*.) This sequence continued over the next 13 *years*, where the Examiner consistently rejected the application as unpatentable in 14 non-final or final rejections (not counting Advisory Actions), and the applicant submitted further arguments and amendments to try to secure a patent, reminiscent of the proverb, "If at first you don't succeed, try, try, try again." (*See id*. at 1-4.) The application even went abandoned at one point. (*See id*. at 2.) Eventually the Examiner allowed the application, which issued as the '021 Patent in November 2014, almost 14 years after filing. (*See* Doc. No. 1-1 at 19.)

Claiming the priority benefit of the '021 Patent's application, the '642 Patent was applied for (on continuation application no. 14/548,972) just before the '021 Patent issued. (Doc. No. 1-2 at 55.) This application had a much shorter and less eventful prosecution, issuing as the '642 Patent in July 2017. (*See id*.; '642 Patent Transaction History, attached herein as Exhibit 2.)

B. Disclosed Invention

The Patents-in-Suit share the same drawings and virtually the same written description, though their claims differ in scope. (*Compare* '021 Patent, Doc. No. 1-1 *with* '642 Patent, Doc. No. 1-2.) Thus, unless otherwise necessary, citations here to the written description will be to the '021 Patent. The Patents-in-Suit describe a process for taking a DNA sample that contains genetic material from more than one contributor and analyzing the sample to determine the genotype[2] of the contributors. (*See* '021 Patent Abstract, Doc. No. 1-1 at 19; Compl., Doc. No. 1 at 4 (¶¶ 14-15).) In other words, the described process is supposed to take a DNA mixture sample, which has

[2] An individual's overall collection of genes is known as that individual's genotype. *Genetic Tech. v. Merial L.L.C.*, 818 F.3d 1369, 1371 (Fed. Cir. 2016). Other than identical twins, each individual has a unique genotype, with alleles inherited from both parents. *See id*. at 1372. Alleles are the various alternative forms of a gene. *Id*. The site or position on a chromosome occupied by a particular gene is the genetic locus (plural loci). *Id*. at 1371.

the DNA of its contributors mixed together, and "deconvolute" it (or mathematically separate into constituent parts) so that the genotype of each contributor is separately identified and can be compared against a suspect. (*See* '021 Patent, Doc. No. 1-1 at 29 (2:9-37[3]).)

At the heart of the disclosed process is the following equation:

$$d = G \cdot w + e \qquad \textit{Eq. 1}$$

(*See id*. at 31 (5:19).) In this equation:

- d is a column vector that lists the measured peak amount of each allele[2] for each analyzed locus[2] in the DNA mixture sample. In other words, d mathematically represents or quantifies the DNA mixture sample;
- G is a matrix that combines, as separate column vectors, the genotypes of each contributor to the DNA mixture sample. Each column of G lists each allele for each analyzed locus for one contributor;
- w is a column vector that lists the proportion of the DNA mixture sample that was contributed by each contributor; and
- e is an error term that explains the difference between what was actually observed (in d) and what was theoretically expected under ideal conditions (by multiplying G by w). Real-world limitations account for this difference.

(*See id*. (5:14-50).)[4] This equation simply expresses, in mathematical form, the natural law of DNA mixtures (namely, that when DNA from separate individuals is combined, the resulting DNA mixture is just the weighted sum of the separate contributors). (*See id*. at 30 (4:48-51, 4:57-66).)

[3] Patent specification citations are in *column:line* format for more precise location.

[4] A more-descriptive version of *Eq. 1* is shown at 6:15, with a specific example for one locus shown at 6:24. (*Id*.) A more descriptive version of *Eq. 1* for two loci is shown at 6:49, with a specific example shown at 6:60. (*Id*.)

The Patents-in-Suit explain that crime-scene DNA samples typically have some number of contributors, where the genotypes of all but one are known; for example, a DNA sample in a rape case has two contributors, where the genotype of the victim-contributor is known but the genotype of the rapist-contributor is unknown. (*See id*. at 33 (9:30-34, 10:46-61).) Using the nomenclature of *Eq. 1*, *d* is known (it is the quantified crime-scene DNA sample) and one of the column vectors of *G* is known (the victim's genotype), but the other column vector of *G* (the rapist's genotype) and *w* (the proportions of the DNA sample contributed by the victim and rapist) are unknown. Because there is one equation but two unknowns, finding the solution would require evaluating a very large number of possible solutions, which would take a very long time, according to the Patents-in-Suit. (*See id*. (9:41-57).)

The disclosed process addresses this problem as follows. First, *Eq. 1* is rewritten in expanded form to allow isolation of the unknowns:

$$d = w_A \cdot a + w_B \cdot b + e \qquad \text{Eq. 2}$$

where *a* and *b* are the column vectors of *G* corresponding to the genotype of the two contributors A (the victim) and B (the rapist), respectively, and where w_A and w_B are the values of *w* corresponding to A and B, respectively. (*See id*. at 31 (5:32-49), 33 (10:19-29).) While *d* and *a* are known, w_A, w_B, and *b* are unknown. However, the sum of the contributors' weights must equal 1 (i.e., the proportion contributed by A plus the proportion contributed by B must equal the entire amount), so w_B can be rewritten as $1-w_A$. (*See id*. at 32 (8:43-44), 33 (10:29).) Making this substitution in *Eq. 2* and dropping the error term *e* (since ideally the expected data would equal the observed data) results in:

$$d = w_A \cdot a + (1 - w_A) \cdot b \qquad \text{Eq. 3}$$

where *d* and *a* are known and *b* and w_A are unknown.

Next, *Eq. 3* is rearranged to solve for *b* (the unknown contributing genotype) as a function of w_A (the proportion of the DNA mixture sample contributed by A):

$$b(w_A) = (d - w_A \cdot a) / (1 - w_A) \qquad \text{Eq. 4}$$

(*See id*. at 33 (10:30-39),[5] 34 (11:16).) Then, *Eq. 4* is evaluated throughout the entire range of w_A (i.e., for all values of w_A between 0 and 1) to determine what would the calculated genotype of the unknown contributor be at that w_A. (*See id*. at 33 (10:62-67), 34 (11:11-16, 11:28-30, 11:55-56).)

To determine which w_A value is likely the correct one, the disclosed process tests two hypotheses. The first hypothesis assumes that unknown contributor B is a homozygote[6] and assigns B's genotype a value of 2 for the allele of $b(w_A)$ that has the highest peak and assigns a value of 0 for all other alleles of $b(w_A)$ at that locus, repeating at each locus. ('021 Patent, Doc. No. 1-1 at 34 (11:32-35).) The second hypothesis assumes that unknown contributor B is a heterozygote and assigns B's genotype a value of 1 for the two alleles of $b(w_A)$ that have the highest peaks and assigns a value of 0 for all other alleles of $b(w_A)$ at that locus, repeating at each locus. (*Id*. (11:38-41).)

The disclosed process then calculates the deviation between the calculated $b(w_A)$ and the assumed genotype of B for each of the two hypotheses at each locus. (*Id*. (11:30-43).) The process then compares the two deviations for the two hypotheses and selects the hypothesis with the smaller deviation as likely being the correct one. (*See id*. (11:44-46).) In other words, the hypothesis for B's genotype that deviates the least from B's calculated genotype is assumed to be

[5] The Patents-in-Suit are not consistent in their nomenclature. For example, the genotype of A is sometimes written as *gA* and sometimes as *a*. (*Compare id*. at 33 (10:36-39) *with id.* at 34 (11:11-16).)

[6] A person is a homozygote if both parents contributed the same allele to a particular locus and a heterozygote if each parent contributed a different allele at that locus. *United States v. Williams*, 382 F. Supp. 3d 928, 930 n.4 (N.D. Cal. 2019). (*See* '021 Patent, Doc. No. 1-1 at 31 (5:43-47), 48 (40:48-52).)

the correct one. The process then sums the smaller deviation at each locus across all loci. (*Id*. (11:47-54; called the "heuristic function").) Then, the total deviation is evaluated (in other words, the above-described algorithm is executed) for the entire range of w_A (between 0 and 1), searching for the value of w_A that results in the smallest total deviation, which is assumed to be the correct w_A. (*See id*. (11:55).)

Having ascertained w_A, all of the variables of *Eq. 3* and *Eq. 4* are now known except for *b*, so evaluating *Eq. 4* gives *b*, which is the genotype of the unknown contributor B – the information sought to be obtained in the first place. (*See id*. (11:55-56); *id*. at 33 (9:32-38).) Because of the matrix-vector multiplication (e.g., $G \cdot w$ in *Eq. 1*), the Patents-in-Suit call this process "Linear Mixture Analysis" or LMA. (*See id*. at 29 (1:21-25, 1:55-62), 30 (4:55-56), 31 (5:15-19, 5:32-39, 6:9-15), 32 (7:27-38).)

The error of the linear model (with the calculated genotype) can be analyzed using standard methods (e.g., calculating a variance). (*See id*. at 35 (14:5-30).) Also, the probability and likelihood ratios of the linear model and calculated genotype can be evaluated using standard statistics and probability methods, for proper explanation of the forensic analysis, e.g., in a criminal case. (*See id*. at 37-40 (18:62-19:21, 19:62-23:40).)

III. APPLICABLE LAW

Subject matter eligibility under 35 U.S.C. § 101 may be determined at the Rule 12(b)(6) stage. *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 765 (Fed. Cir. 2019). Rule 12 dismissal is appropriate when, assuming all well-pleaded facts are true and drawing all reasonable inferences in favor of the plaintiff, the complaint fails to allege sufficient facts to state a claim that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1017 (Fed. Cir. 2019).

Section 101 delineates the subject matter eligible for patent protection. *ChargePoint*, 920 F.3d at 765. However under important and longstanding judicial exceptions, laws of nature, natural phenomena, and abstract ideas are not patentable. *Id*.; *SAP Am. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 2747 (U.S. June 24, 2019) (No. 18-1199). These exceptions exist because monopolizing the basic tools of scientific work might impede innovation more than promote it. *Athena Diagnostics, Inc. v. Mayo Collaborative Serv.*, 915 F.3d 743, 749 (Fed. Cir. 2019).

These exceptions are analyzed under the *Alice* test. A claim falls outside § 101 where: (1) it is "directed to" one of the exceptions, and (2) the particular elements of the claim, considered both individually and as an ordered combination, do not add enough to transform the nature of the claim into a patent-eligible application of the ineligible matter. *SAP Am.*, 898 F.3d at 1166-67 (citing *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014)). The first stage of the *Alice* test looks at the focus of the claims and their character as a whole. *Id*. at 1167. The second stage of the test searches for an "inventive concept" – i.e., whether additional claim elements (other than the exception itself) sufficiently ensure that the patent in practice amounts to significantly more than a patent on the ineligible concept itself. *ChargePoint*, 920 F.3d at 765, 774.

IV. DISCUSSION

The Complaint alleges that Defendants infringe claim 1 of the '021 Patent and claim 1 of the '642 Patent but does not specifically identify infringement of any other claims of the patents. (*See* Compl. Doc. No. 1 at 5-9, 12-14.) The '021 Patent has only two independent claims (1 and 66), and the '642 Patent has only one independent claim (1). ('021 Patent, Doc. No. 1-1 at 51-53; '642 Patent, Doc. No. 1-2 at 87-88.) The independent claims of the '021 Patent are extremely similar. The only differences appear in steps (j) and (k), where claim 1 computes and uses a

probability but claim 66 calculates and uses a likelihood ratio. (*See* '021 Patent, Doc. No. 1-1 at 51-53.) But a probability and a likelihood ratio are related concepts, as explained in the Patents-in-Suit, because a likelihood ratio is just a ratio of probabilities. (*See id*. at 38 (19:67-20:40).)

These three independent claims are representative of all the claims because all are substantially similar and linked to the same abstract idea, with the dependent claims only adding minor limitations that do not alter the character of the analysis. *See TS Patents LLC v. Yahoo! Inc.*, 279 F. Supp. 3d 968, 988-89 (N.D. Cal. 2017) (citing *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1348 (Fed. Cir. 2014)) (analyzing the only claim asserted in complaint as representative), *aff'd*, 731 F. App'x 978 (Fed. Cir. 2018); *Natural Alternatives Int'l v. Allmax Nutrition, Inc.*, 258 F. Supp. 3d 1170, 1181 n.10 (S.D. Cal. 2017) (same); *Maxon, LLC v. Funai Corp.*, 255 F. Supp. 3d 711, 715-16 (N.D. Ill. 2017) (same), *aff'd*, 726 F. App'x 797 (Fed. Cir. 2018). Thus, this motion will focus on these three representative claims.

A. *Alice* Stage One – The Claims Are Directed to Abstract Ideas.

1. Claim 1 of the '642 Patent

Of the three independent claims, claim 1 of the '642 Patent is the broadest and is considered first. (*Compare* '021 Patent, Doc. No. 1-1 at 51-53 *with* '642 Patent, Doc. No. 1-2 at 87.) It reads:

> 1. A method of analyzing a biological sample comprised of the steps:
>
> (a) obtaining a biological sample that contains DNA;
>
> (b) amplifying the DNA to produce a product;
>
> (c) detecting the product to generate data, where the data can be explained by more than one genotype value;
>
> (d) assuming a genotype value which is stored in a nontransient memory;
>
> (e) deriving with a computer a variance of the amplification; and

> (f) determining a likelihood using a computer in communication with the memory, where the likelihood is defined as a probability of observing the generated data, and said probability depends on the genotype value and the variance.

('642 Patent, Doc. No. 1-2 at 87.) This method boils down to the following:

- collect DNA sample data (steps (a)-(c)),
- guess a possible contributing genotype (step (d)), and
- analyze the accuracy of the guess (how close the guess is (step (e)) and how likely was it a contributor to the DNA sample (step (f)).

This is all abstract.

The Federal Circuit has explained that claims focusing on collecting information or data, analyzing it, and displaying certain results of the collection and analysis are directed to an abstract idea. *SAP Am.*, 898 F.3d at 1167; *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1340 (Fed. Cir. 2017); *see also Parker v. Flook*, 437 U.S. 584, 595 (1978) ("If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method" fails § 101.); *Digitech Image Tech. v. Elec. for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (using mathematical algorithm to manipulate existing information to generate additional information is not eligible); *Burnett v. Panasonic Corp.*, 741 F. App'x 777, 780 (Fed. Cir. 2018) (process that takes data, applies an algorithm, and ends with a new form of data is an abstract idea), *cert. denied*, 139 S. Ct. 600 (U.S. Dec. 3, 2018) (No. 18-414). Information as such is an intangible and abstract. *SAP Am.*, 898 F.3d at 1167. Collecting information (even when limited to particular content) is also abstract, and so is analyzing information by mathematical algorithms, without more. *Id.*; *Elec. Power Grp. v. Alstom S.A.,* 830 F.3d 1350, 1353-54 (Fed. Cir. 2016).

In *SAP Am.*, the claims, which were patent-ineligible, were drawn to a series of mathematical/statistical calculations on certain information and presenting the results in the plot of a probability distribution function, for use in the finance field. *See id*. at 1163-65. Those claims are analogous to claim 1 of the '642 Patent, which also takes information and applies mathematical calculations to that information, in the field of forensic DNA. *See also Coffelt v. NVIDIA Corp.*, 680 F. App'x 1010, 1011 (Fed. Cir. 2017) (mathematical algorithm for calculating and comparing regions in space is an ineligible mental process).

Steps (a)-(c) of claim 1 simply recite preliminary and routine actions that are done to obtain data on which the mathematical algorithms can be executed (*see* Compl., Doc. No. 1 at 13 (stating that steps (a)-(c) are a "necessary precondition" to running forensic genotyping software)) – certainly those steps (further discussed under *Alice* stage two below) are not the focus of the alleged invention. Rather, the patent specification makes clear that the alleged improvement here is in the "mathematical analysis of information," *see SAP Am.*, 898 F.3d at 1168, as implemented in steps (d)-(f):

- The present invention includes a quantitative analysis method that describes the mixture problem as a *linear matrix equation*. One name for this novel DNA analysis approach is "Linear Mixture Analysis," or "LMA". Unlike previous methods, the *mathematical LMA model* uses STR data from all the loci simultaneously for greater robustness. The *linear mathematics permits rapid computer calculation*, and provides a framework for *statistical analysis*. An associated *error analysis* can measure the quality of the overall solution, as well as the utility of each contributing locus. ('642 Patent, Doc. No. 1-2 at 64 (1:65-2:7) (emphasis added).)

- Others have computed mixture weights by minimizing parameters at single loci . . . [citing prior art reference]. In the LMA model, this early work can be reinterpreted as minimizing at a single locus the *sum of squares deviation* $\|d-G\cdot w\|^2$ *over* w for each feasible *integer-valued genotype matrix* G. This prior art has a limited single-locus view of the data, which restricts the amount of derivable useful information; there is no known way to combine the separate single locus partial solutions into one global optimum. Moreover, such prior art does not make special use of the known reference genotypes, which contain much valuable information. *LMA improves on such earlier mixture methods by providing a mathematical basis*

that can use the data from all the loci simultaneously in a *rapid optimized numerically computed global minimization*. Moreover, LMA permits the genotype matrix entries to assume any possible value, and not just integers. (*Id*. at 67-68 (8:59-9:10) (emphasis added).)

- A highly useful effect of the invention is that *variances* and *standard deviations* can be *computed directly from the experimental data* in order to quantify a confidence in the results. (*Id*. at 71 (15:33-36) (emphasis added).)

- This problem (more than one unknown contributor) is quite hard, and not feasibly solved in the prior art. . . . However, with a *novel combination of mathematics, computation, and information*, the described invention can usefully solve this problem. (*Id*. (15:63-64, 16:7-9) (emphasis added).)

- The *determination of* $Pr\{d|a,b_i\}$ does not appear in the prior art of DNA mixture analysis. Indeed, it is desperately needed, but conspicuously absent, in a seminal mixture analysis paper . . . [citing prior art reference]. However, by *using the linear modeling invention*, these *probabilities can be estimated using the probability estimates already described*. (*Id*. at 74 (21:34-42) (emphasis added).)

- This ability to *compute the LR* . . . by appropriately weighting the *prior probabilities* $Pr\{b_i\}$ based on the weight of evidence in the data $Pr\{d|a,b_i\}$ represents a strikingly useful *advance over the prior art*. (*Id*. (22:49-58) (emphasis added).)

- By providing a (*novel*) means for *computing a mixture likelihood*, the *invention enables the computation of posterior genotype distributions*. (*Id*. at 79 (31:2-4) (emphasis added).)

- The *invention enables mathematical estimation* of genotypes, together with *statistical certainties*, that overcome the qualitative limitations of the current art, and can lead to greater certainty in human identification with increased likelihood of conviction in problematic cases. (*Id*. at 82 (37:60-64) (emphasis added).)

- The linear mixture analysis and mixture deconvolution methods are designed for *computer-based automation* of DNA analysis. The results are *computed mathematically*, and then can be *presented automatically as tables and figures* via a user interface to the forensic analyst. This analysis and presentation automation provides a mechanism for automated report generation. (*Id*. (38:9-15) (emphasis added).)

- The *mixture deconvolution invention* is therefore quite applicable to SNP data. This is because the *mathematical form of the problem*, and the *linear nature of the data*, are identical to the problem solved above for *any linear mixture model*, as illustrated in depth for STRs. (*Id*. at 84 (42:48-52) (emphasis added).)

See ChargePoint, 920 F.3d at 766-67 (specification can illuminate what claim is directed to); *Intellectual Ventures*, 850 F.3d at 1338 (look at claimed advance over prior art to determine what claim is directed to). Just as in *SAP Am.*, it is clear that the claimed invention is directed to the mathematical algorithm. *See* 898 F.3d at 1168.

In *SAP Am.*, the disclosed mathematical algorithms were limited to a certain field (finance and investments); but limiting the abstract idea to a certain field does not make it any less abstract, and furthermore the "investment" character simply invokes a separate category of abstract ideas. *Id*. at 1168. Likewise, limiting the mathematical algorithms to DNA mixtures is a mere "field of use" limitation that does not render the claims eligible; moreover, such a limitation invokes the separate "natural law" category of abstract ideas, where the involved mathematical formulas simply express (in equation form) the relationship of how DNA from multiple contributors combine in a mixture, as explained in § II.B above. *Cf. Athena* Diagnostics, 915 F.3d at 750 (correlation between autoantibodies in bodily fluid and certain diseases exists in nature apart from any human action and is thus a natural law); *Genetic Tech.*, 818 F.3d at 1375 (correlation between non-coding and coding regions is a universal, inherent feature of human DNA and thus a natural law); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373-74, 1376 (Fed. Cir. 2015) (amplifying fetal DNA and detecting paternally inherited DNA is directed to a natural phenomenon).

As in *SAP Am.*, the claims here are not directed to a new computer or a new physical display; rather, as in *SAP Am.*, the "claimed improvement [is] in a mathematical technique with no improved display mechanism" or improved computer. *See* 898 F.3d at 1167-68. As in *SAP Am.*, "the specification makes clear that off-the-shelf computer technology is usable to carry out the analysis." (*See* '642 Patent, Doc. No. 1-2 at 68 (10:9-10), 76 (25:34-45) (algorithm was

implemented on off-the-shelf Apple computer).) For these reasons, the claim is directed to ineligible abstract ideas.

2. Claim 1 of the '021 Patent

Claim 1 of the '021 Patent reads as follows:

1. A method of analyzing a DNA mixture comprised of the steps:

(a) obtaining a DNA mixture that contains genetic material from at least two contributing individuals;

(b) amplifying the DNA mixture in a DNA amplification process to produce an amplification product comprising DNA fragments;

(c) producing from the amplification product a signal comprising signal peaks from the DNA fragments;

(d) detecting signal peak amounts in the signal, and quantifying the amounts to produce DNA lengths and concentrations from the mixture to form quantitative genotyping data;

(e) assuming a genotype value of alleles for a contributor to the quantitative genotyping data at a genetic locus;

(f) setting a mixture weight value for a relative proportion of the contributors to the quantitative genotyping data;

(g) forming a linear combination of the genotype values based on the mixture weight value;

(h) deriving with a computer a data variance of the amplification process from a model that includes both the quantitative genotyping data and the linear combination;

(i) determining with the computer a probability of the quantitative genotyping data corresponding to a set of suspects from the DNA mixture at the locus using both the linear combination and the data variance value;

(j) computing a probability of a genotype for one of the contributing individuals using the determined probability of the quantitative genotyping data; and

(k) comparing the genotype probability with a set of suspect genotypes to identify a likely suspect.

('021 Patent, Doc. No. 1-1 at 51-52.) Similar to the '641 Patent claim, this claim boils down to:

- collect DNA mixture sample data (steps (a)-(d)),
- guess possible contributing genotypes and the contributor proportions (steps (e)-(f)),
- analyze the accuracy of the guess (how close the guess is (steps (g)-(h)) and how likely were the guessed genotypes contributors to the DNA sample (steps (i)-(j))), and
- use the guess accuracy to identify from a database the likely sample source (step (k)).

The extra steps do not make this claim any less abstract than the '642 Patent claim.

Steps (a)-(d) (corresponding to steps (a)-(c) of the '642 Patent claim) are just preliminary and routine actions that are done to obtain data (namely, quantitative genotyping data) on which the mathematical algorithms can be executed and are not the focus of the alleged invention. (*See* Compl., Doc. No. 1 at 7 (stating that steps (a)-(d) are a "necessary precondition" to running forensic genotyping software).)

Steps (e)-(k) recite the mathematical algorithm disclosed in the Patents-in-Suit. The algorithm takes as inputs the quantitative genotyping data (obtained in step (d)), the guessed/ assumed contributor genotypes (in step (e)), and the relative contributor proportions (called mixture weights, in step (f)). Step (g) is simply the multiplication of genotype matrix *G* by the weight vector *w* (*see* Eq. 1 in § II.B above). (*See* Applicant's June 9, 2014 Reply to December 9, 2013 Office Action, excerpts attached herein as Exhibit 3, at p. 21 (linear combination means *G* times *w*).) Steps (h)-(j) recite additional calculations: calculating a variance (step (h)), calculating one probability (step (i)), and then calculating another probability (step (j)). These are just mathematical calculations. Finally, step (k) is just a "data comparison" step, which is also abstract. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366 (Fed. Cir. 2018) (parsing and comparing data is abstract), *petition for cert. filed*, (Oct. 3, 2018) (No. 18-415); *In re BRCA1- & BRCA2-Based*

Hereditary Cancer Test Patent Litig., 774 F.3d 755, 763 (Fed. Cir. 2014) (comparing DNA sequences is abstract).

As explained above for the '642 Patent, this claim focuses on collecting information, manipulating and analyzing it with mathematical formula and algorithms, and comparing the result, which is all abstract. The specification makes clear, as explained above,[7] that the mathematical algorithm is what the invention is directed to. Though claim 1 here recites a few additional details in its steps, those additional details are also abstract. *See ChargePoint*, 920 F.3d at 771 ("[A]dding one abstract idea to another abstract idea does not render the claim non-abstract."). Thus, the claim is directed to ineligible abstract ideas.

3. Claim 66 of the '021 Patent

As explained above at the start of § IV, claim 66 is the same as claim 1 except for the last two steps ((j)-(k)).[8] The difference is that claim 1 computes and compares a probability, whereas claim 66 calculates and compares a likelihood ratio. Yet a likelihood ratio is just a ratio of probabilities – again, a mathematical formula – so the § 101 analysis is the same for claim 66 as for claim 1 with the same result: claim 66 is directed to ineligible abstract ideas.

B. *Alice* Stage Two – The Claims Recite No Inventive Concept.

Having shown that the claims are directed to ineligible abstract ideas, the remaining stage searches for any "inventive concept" among the claims that could salvage them. If the claims are directed to patent-ineligible concepts, the Supreme Court explained, "we then ask, 'what else is

[7] As noted in § II.B, the Patents-in-Suit share virtually the same written description and drawings (the '642 Patent is a continuation of the '021 Patent), so the specification passages from the '642 Patent also appear in the '021 Patent (though in slightly offset citation locations).

[8] Steps (i) among the two claims also have a minor difference with respect to the placement of the word "data." This appears to be a typographical error in claim 66 that was corrected by a Supplemental Examiner's Amendment but that did not carry through to the patent printing.

there in the claims before us?'" *Alice Corp.*, 573 U.S. at 217. Setting aside the ineligible concepts, do the remaining claim elements provide something inventive, beyond mere well-understood, routine, conventional activity? *Genetic Tech.*, 818 F.3d at 1376; *see also ChargePoint*, 920 F.3d at 774 (abstract idea itself cannot supply the inventive concept). There is no inventive concept in these claims, whether considering the limitations separately or in combination.

1. Claim 1 of the '642 Patent

As explained above, steps (d)-(f) of claim 1 of the '642 Patent recite the ineligible abstract idea (which cannot provide the inventive concept). The preliminary steps (a)-(c) simply describe well-understood, routine, and conventional steps that would be taken by any forensic laboratory analyzing DNA samples. For example, it is self-evident (and thoroughly routine) that before a biological sample can be analyzed, it must first be obtained (step (a)). (*See* '642 Patent, Doc. No. 1-2 at 65 (3:13-15) (DNA is extracted from a sample using standard techniques), 68-69 (10:65-11:5) (rape cases typically involve obtaining mixed DNA sample).)

Likewise, DNA amplification (step (b)) was well-understood, routine, and conventional as early as 1994 or earlier. *See Roche Molecular Sys. v. CEPHEID*, 905 F.3d 1363, 1366 (Fed. Cir. 2018); *Ariosa Diagnostics*, 788 F.3d at 1377 (PCR was routine in 1997). (*See* '021 Patent, Doc. No. 1-1 at 20 (citing Reiss et al., "The effect of replication errors on the mismatch analysis of *PCR-amplified DNA*," published in 1990) (emphasis added); '642 Patent, Doc. No. 1-2 at 65 (3:32-52) (discussing DNA amplification (PCR technique) using existing multiplex primer sets).)

And quantifying the amplified DNA in data form (step (c)) was also routine and conventional. (*See* '642 Patent, Doc. No. 1-2 at 64 (1:22-64) (discussing existing PCR-based STR typing systems that generate STR peak data from DNA samples and quantitatively analyze it), 65

(4:17-32) (discussing quantitation of the allelic peaks of the amplified DNA using existing software programs and techniques).) There is nothing inventive in these preliminary steps.

Steps (d)-(f) recite performing the algorithm using a "nontransient memory" and a "computer." These are just generic components that were well-known, routine, and conventional in 2001 (the priority date of the Patents-in-Suit). (*See* '642 Patent, Doc. No. 1-2 at 68 (10:9-10), 76 (25:34-45) (algorithm was implemented on off-the-shelf Apple computer).) *See SAP Am.*, 898 F.3d at 1170 (already-available computers are routine and conventional); *Smart Sys. Innovations, LLC v. Chi. Transit Auth.*, 873 F.3d 1364, 1374-75 (Fed. Cir. 2017) (generic computer components such as memory and processor are not inventive concepts); *Elec. Power Grp.,* 830 F.3d at 1355.

Furthermore, simply limiting the claims to a particular field of use or technological environment is insufficient to transform them into patent-eligible applications of their core abstract idea, as already discussed above in § IV.A. *See Alice Corp.,* 573 U.S. at 222-23; *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1334 (Fed. Cir. 2012). Thus, limiting the mathematical algorithm to the forensic DNA field is insufficient to make the claims patent-eligible.

2. Claim 1 of the '021 Patent

Analysis of claim 1 of the '021 Patent leads to the same result. Steps (e)-(k) recite the ineligible abstract idea (which cannot provide the inventive concept). They further recite performing the algorithm using a generic "computer," which is routine and conventional.

The preliminary steps (a)-(d) are well-understood, routine, and conventional for the same reasons as discussed above for claim 1 of the '642 Patent. Steps (a)-(b) of claim 1 of the '021 Patent correspond to steps (a)-(b) of claim 1 of the '642 Patent. Step (c) of claim 1 of the '642 Patent (detecting the amplified DNA product to generate data) is split over two steps ((c)-(d)) in claim 1 of the '021 Patent, but with no change in effect: step (c) generates a signal (with peaks)

from the amplified DNA product, and step (d) then quantifies the peaks to generate data. The specification discloses that these steps were done with existing technology. (*See* '021 Patent, Doc. No. 1-1 at 30 (3:31-4:25) (existing sequencers take amplified DNA and generate signals, which are analyzed and quantified by existing software to produce data files).) No inventive concepts appear in this claim.

3. Claim 66 of the '021 Patent

Because the only difference in claim 66 from claim 1 is steps (j)-(k), the above analysis of claim 1 applies to claim 66. Steps (j)-(k) only recite part of the ineligible abstract algorithm and thus cannot provide the inventive concept.

4. Dependent Claims

None of the dependent claims in either patent add any inventive concept either. From the '642 Patent, the following claims simply recite additional mathematical operations and abstract ideas: 2 (calculating a likelihood ratio), 3-4 (calculated hypothesis is of an individual contributing DNA to the analyzed sample, for purposes of identifying the individual), 5 (calculating a likelihood ratio for different hypotheses), 7 (forming a linear combination (i.e., G times w)), 8 (setting a contribution proportion value), 9 (multiplying the linear combination by the contribution proportion weights), 12 (including a conditional parameter to the likelihood calculation), 14 (using likelihood for comparisons with a database), 15 (Markov chain Monte Carlo algorithm), and 16 (deriving variance with calibration). *See SAP Am.*, 898 F.3d at 1169 (dependent claims that recite further statistical methods add nothing outside the abstract realm). And the following claims recite well-known, routine, and conventional limitations to the preliminary steps: 6 (analyzed sample is a mixture from multiple individuals), 10 (quantified DNA data is from short tandem repeat (STR) analysis, *see* '642 Patent, Doc. No. 1-2 at 64 (1:48-64)), 11 (quantified DNA data contains PCR

stutter, *see id*. at 65 (4:33-39)), and 13 (repeating amplification step, *see id*. (3:40-41) (increasing PCR amplification cycles)). Nothing inventive appears in these claims.

The same is true for the dependent claims of the '021 Patent. The following claims simply recite additional mathematical operations and abstract ideas: 4 (linear model ($d = G \cdot w$)), 6 (iterative algorithm), 7-8 (matrix values), 9 (subtraction algorithm), 10-13 (parameters of linear model), 14 (probability calculation), 15 (computing relative weight), 16 (statistical confidence), 19 and 21 (executing algorithm within one hour), 24 (repeating analysis), 26 (assumed genotypes picked from database), 27 and 59 (ranking genotypes), 29-33 and 44 (various probability distributions), 39 (varying amount of data used), 40 (numeric representation of genotype), 45-48 (varying number of genotypes in linear model), 49-53 (variance parameters and calculation), 54 (calculating probability with simulated genotype), 55-57 (probability function), 60 (separating data into components with probability), 67 and 69 (likelihood ratio calculation), and 68 and 70 (using likelihood ratio for purposes of identifying an individual). Claims 2-3 recite ineligible natural laws, per the specification disclosure. (*See* '021 Patent, Doc. No. 1-1 at 30 (4:46-51) (DNA amplification yields fragments and corresponding signals that are proportional to the relative contribution proportions).)

Lastly, the following claims recite well-known, routine, and conventional pre- or post-solution activity (*see Dealertrack*, 674 F.3d at 1334): 5 (show the genotype vector and weight matrix visually), 17 and 61 (record results in a report), 18 (suspect genotypes include convicted offenders), 20 and 22 (generic computing device with memory), 23 (single nucleotide polymorphism (SNP) markers, *see* '021 Patent, Doc. No. 1-1 at 48 (40:34-40)), 25 (DNA mixture sample has genetic material from multiple individuals), 28 and 36 (low copy number PCR, *see id.* (39:11-25)), 34-35 (quantified DNA data is from short tandem repeat (STR) analysis), 37 (detected

signal peak amounts are from peak height or area), 38 (repeating experiments), 41-43 (quantified data includes artefacts, *see id*. at 30 (4:26-45), 48 (39:26-28)), 58 (show probability visually), 62-63 (store genotypes and their probabilities on a database), 64 (use probabilities as investigative leads), and 65 (compute probabilities at service center). No inventive concept appears in these dependent claims either. Thus, because all of the claims of the Patents-in-Suit are directed to patent-ineligible subject matter and contain no inventive concept, they are invalid under § 101.

V. CONCLUSION

Section IV.A.1 quoted portions of the Patents-in-Suit' specification alleging the novelty and innovativeness of the invention. However, even groundbreaking, innovative, or brilliant techniques are not patentable if their innovation is in ineligible subject matter. *SAP Am.*, 898 F.3d at 1163. As explained, the Patents-in-Suit fail the requirements of § 101. By discussing these requirements in this motion, Defendants do not concede that the invention is actually novel and innovative, that all other patentability and enforceability requirements have been met, or that Defendants infringe, and those issues will be addressed as appropriate. However, because the Patents-in-Suit try to cover subject matter that is simply not eligible for patent protection, Defendants respectfully request that the Court grant this motion and dismiss Plaintiff's Complaint with prejudice, without the need for further waste of resources by the Court or the parties.

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EMERSON THOMSON BENNETT, LLC
s/ Sergey Vernyuk
Sergey Vernyuk (Ohio Bar # 0089101)
sv@etblaw.com
1914 Akron-Peninsula Rd.
Akron, Ohio 44313
(330) 434-9999 – Telephone
(330) 434-8888 – Facsimile
Co-counsel for Defendants Institute of Environmental Science and Research Limited and NicheVision Inc.